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| A 000 | INITIAL COMMENTS | A 000 | | |

Oklahoma State Department of Health surveyors conducted an unannounced CMS Patient Safety Initiative survey on 08/11/2015 for the focus areas related to the Conditions of Participation for Infection Control, Quality Assessment and Performance Improvement (QAPI) and Discharge Planning. During the course of this survey, immediate jeopardy was identified in the surgery department for deficient practices related to infection control, physical environment and surgical services.

Based on observations, interviews and document reviews, it was determined that the deficient practices found in the surgery department posed immediate jeopardy to the health and safety of patients and had the potential for harm, serious injury or death. It was determined the hospital failed to provide surgical services in a manner to ensure patients were not exposed to pervasive environmental hazards and unacceptable infection control practices.

On 08/12/2015 at 9:30 a.m., the Oklahoma State Department of Health (OSDH) notified the CMS Regional Office in Dallas,Texas of the immediate jeopardy findings. The Regional Office concurred that immediate jeopardy conditions existed and authorized a full re-certification survey.

At 1:40 p.m., the hospital administrator was notified the surveyors were requesting a meeting with him and other parties as he determined necessary, so that urgent survey findings could be discussed. At 2:07 p.m., the administrator and members of the hospital leadership team were informed of the immediate jeopardy conditions

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identified in the surgery department and that the OSDH surveyors would expand the survey from a Patient Safety Initiative survey to a full re-certification survey.

On 08/17/2015 at 3:10 p.m., the hospital submitted a plan of removal for the immediate jeopardy findings in the surgery department. The hospital's plan was not accepted by OSDH because it did not remove the immediacy to the conditions present within the surgery department.

On 08/18/2015 at 10:45 a.m., the hospital submitted a written plan of removal to immediately cease all surgical services. The plan of removal was accepted by OSDH. At 11:10 a.m., the surveyors verified the surgery department was closed. As a result, the hospital was no longer in immediate jeopardy, but remained in condition level non-compliance for 482.41 Condition of Participation: Physical Environment, 482.42 Condition of Participation: Infection Control and 482.51 Condition of Participation: Surgical Services.

During the course of the survey, other condition level deficiencies were found for:

482.12 Governing Body
482.21 Quality Assessment and Performance Improvement
482.25 Pharmaceutical Services

The following abbreviations may be found within this document:

AAMI = The Association for the Advancement of Medical Instrumentation
AORN = The Association of periOperative

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| A 000 | Continued From page 2<br>Registered Nurses<br>ASGE = American Society for Gastrointestinal Endoscopy<br>ASHE = American Society for Healthcare Engineering<br>CDC = Centers for Disease Control and Prevention<br>CMS = Center for Medicare & Medicaid Services<br>CT Scan = Computerized Tomography<br>EPA = Environmental Protection Agency<br>FDA = Food and Drug Administration<br>FGI = Facility Guidelines Institute<br>HEPA = High Efficiency Particulate Arrestance<br>HLD = High Level Disinfection<br>HVAC = Heating, Ventilation and Air Conditioning<br>ICP = Infection Control Professional<br>IUSS = Immediate Use Steam Sterilization<br>IV = Intravenous<br>NFPA = National Fire Protection Association<br>OPO = Organ Procurement Organization<br>OR = Operating Room<br>OSDH = Oklahoma State Department of Health<br>OSHA = Occupational Safety and Health Administration<br>QAPI = Quality Assessment and Performance Improvement<br>RN = Registered Nurse<br>RT = Respiratory Therapy<br>SP or SPD = Sterile Processing or Sterile Processing Department<br>SSI = Surgical Site Infection | A 000 | | |
| A 043 | 482.12 GOVERNING BODY<br><br>There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the | A 043 | | |

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| A 043 | Continued From page 3 | A 043 | | |

functions specified in this part that pertain to the governing body ...

This CONDITION is not met as evidenced by:
Based on review of hospital documents, staff interviews and surveyor observations, the hospital's governing body failed to:

a. ensure the hospital developed and implemented an effective and active Quality Assessment and Performance Improvement program. See tag A-0263;

b. require the evaluation of the performance of medical staff during the reappointment process and failed to ensure a qualified medical staff member was appointed as chief of nuclear medicine services. See tag A-0340 and tag A-1028;

c. oversee the provision of pharmaceutical services. See tag A-0490;

d. maintain the hospital to ensure safe and sanitary conditions for patients and staff. See tag A-0700 and Life Safety Code survey findings;

e. ensure the hospital developed and implemented an effective infection control program to prevent, control and investigate infections and communicable diseases in patients and staff. See tag A-0747;

f. ensure surgical services where provided according to accepted standards of practice. See tags A-0940, A-0700 and A-0747; and

g. the governing body failed to ensure the hospital identified and evaluated all contracted services

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| A 043 | Continued From page 4 | A 043 | | |

for quality and safety. These deficient practices had the potential to affect all patients receiving services at the hospital.

Findings:

A hospital document titled "Bylaws of Grady Memorial Hospital," revised in September 2012, documented, "...The name of the body of individuals appointed to exercise the required supervision of the hospital's activities shall be the 'Board of Trustees' of Grady Memorial Hospital. The property, business and affairs of the hospital shall be managed under the direction of the Board..."

1. The governing body failed to ensure the hospital had a comprehensive and effective quality assessment and performance improvement program to improve health outcomes and reduce medical errors.

2. The governing body failed to take action when the medical staff due for reappointment were not evaluated and failed to appoint a qualified medical staff member as chief of nuclear medicine.

3. The governing body failed to ensure the pharmacist maintained current licensure and evidence of on-going continuing education related to pharmacy practice; failed to ensure the pharmacist was evaluated annually for performance and competency; failed to ensure the development and implementation of policies and procedures to minimize medication errors and adverse events based on accepted standards of practice; failed to require the pharmacist to provide oversight of drugs and

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| A 043 | Continued From page 5 | A 043 | | |

biologicals within the surgery services department and the governing body failed to require pharmacy services to be an active participant in the QAPI program.

4. The governing body failed to ensure the condition of the hospital was constructed, maintained and repaired to ensure the safety and health for patients and staff; preventive maintenance, testing and repairs were completed in a timely manner for all hospital equipment; and failed to develop and implement an emergency preparedness plan.

5. The governing body failed to ensure proper temperature, humidity, ventilation and filtration in the surgery department to inhibit the growth and spread of pathogens; ensure the hospital followed national standards of practice and manufacturers' guidelines for surgical instrument decontamination, high level disinfection and sterilization; ensure aseptic conditions in all parts of the surgery department; require surgical supplies to be stored in a manner to ensure integrity and sterility; provide hand washing facilities as required for staff in the surgery department; provide emergency eye wash stations as required for staff in the surgery department; ensure surgery staff were trained and verified competent in the infection control practices related to their job duties; require comprehensive infection control surveillance, reporting and corrective actions for all areas of the hospital; and the governing body failed to require the hospital's infection control committee to thoroughly investigate potential causes of surgical site infections.

6. The governing body failed to ensure all surgical

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procedures were performed under acceptable conditions and in locations appropriate for surgery; ensure the hospital developed an organizational chart for the surgery department and appoint a physician chief of surgery; ensure that surgical services were integrated into the hospital's QAPI program; require the hospital to provide a written and approved scope of surgical services; and the governing body failed to require the hospital to develop and implement current policies and procedures for the provision of surgical services.

7. The governing body failed to ensure the hospital identified and evaluated all contracted services provided to the hospital. On 08/12/2015, the hospital was asked to provide a list of all contracted services. The list provided did not include all contracted services the surveyors identified in the hospital. The hospital had failed to identify the contractors who provided surgical instrument reprocessing, air handling services, sleep study services, the medical physicist and the company that provided dosimetry services.

On 08/12/2015, the surveyors became aware that the individual who provided preventative maintenance for the hospital's equipment was also a contractor.

The hospital did not maintain files for contracted employees to include health and immunization records, training and education, previous experience and competency evaluation.

The hospital failed to periodically evaluate the services provided by the contract service providers.

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| A 263 | Continued From page 7 | A 263 | | |
| A 263 | 482.21 QAPI<br><br>The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.<br><br>The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.<br><br>The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.<br><br>This CONDITION is not met as evidenced by:<br>Based on observations, interviews and document review, it was determined the governing body failed to ensure the hospital had a comprehensive and effective quality assessment and performance improvement program to improve health outcomes and reduce medical errors.<br><br>Findings:<br><br>1. The hospital had a QAPI plan for 2015 that did not include all departments and services and did not reflect the complexity of services the hospital provided.<br><br>2. The QAPI program meeting minutes did not document the hospital had identified its own problematic areas. Safety and infection control committee meeting minutes documented some | A 263 | | |

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environmental problems were identified by staff. It could not be verified through the QAPI documents provided to the surveyors that these problems were brought to the attention of the QAPI committee.

3. The QAPI program did not focus on improving health outcomes and the prevention and reduction of medical errors. On 08/18/2015, the pharmacist was asked to provide documentation of pharmacy QAPI indicators, QAPI activities and all pharmacy reports to the hospital's QAPI committee. No documentation was provided.

4. There was no documentation found in the QAPI committee meetings minutes that medication errors, adverse reactions and other untoward medication administration events were reviewed in 2014 or 2015. There was no documentation of any medical errors in the QAPI meeting minutes.

5. The hospital provided documents that included quality related data collection. However, the QAPI program failed to progress any projects past the data collection phase. The QAPI meeting minutes from June 2014 through July 2015 did not contain evidence performance improvement actions were implemented.

6. On 08/18/2015, staff C stated a Joint Conference committee comprised of the chief of staff, three board members and the hospital administrator regularly met before the Board of Trustee meetings. Staff C stated the committee met to review medical executive committee and QAPI meeting minutes and relevant documents.

The surveyors requested and reviewed the Joint

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| A 263 | Continued From page 9<br>Conference meeting minutes from July 22, 2014 through June 23, 2015. The meeting minutes had no documentation the committee addressed the QAPI program or QAPI activities. | A 263 | | |
| A 340 | 482.22(a)(1) MEDICAL STAFF PERIODIC APPRAISALS<br><br>The medical staff must periodically conduct appraisals of its members.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of hospital documents and interviews with staff, the hospital failed to evaluate the performance of practitioners during the reappointment process to determine if the credentialing status and privileges were appropriate. This deficient practice was found in seven out of eight credentialing files reviewed.<br><br>Findings:<br><br>The medical staff bylaws, effective 11/19/2013, documented, "... Every two years, the Medical Executive Committee and Governing Body shall consider reappointment of each practitioner scheduled for periodic appraisal... Each recommendation concerning the reappointment of a medical staff appointee and the clinical privileges to be granted upon reappointment shall be based, as applicable, upon such appointee's ... 10 outcomes of peer review activities..."<br><br>Seven of the eight medical staff credentialing files reviewed did not contain documentation of peer review.<br><br>On the 08/18/2015 at 2:00 p.m., staff JJ stated he was responsible for the credentialing files. He | A 340 | | |

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| A 340 | Continued From page 10<br>was asked for the peer review documentation for the medical staff files selected. No documentation was provided.<br><br>Minutes for the hospital's Quality Assessment Performance Improvement and Patient Safety Council, dated 06/03/2015, documented, "... [Physician name omitted] was supposed to review the surgeons' charts and that is not occurring..." There was no documentation of actions taken by the governing body as a result of this finding. | A 340 | | |
| A 490 | 482.25 PHARMACEUTICAL SERVICES<br><br>The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, staff interview and document review, it was determined the hospital failed to:<br><br>a. ensure the pharmacist maintained current licensure and evidence of on-going continuing education related to pharmacy practice;<br><br>b. show evidence the pharmacist was evaluated annually for performance and competency;<br><br>c. develop and implement policies and procedures to minimize medication errors and | A 490 | | |

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adverse events based on accepted standards of practice;

d. ensure the pharmacist provided adequate oversight of drugs and biologicals within the surgery services department; and

e. pharmacy services were integrated into the hospital-wide quality assessment performance improvement (QAPI) program.

Findings:

1. On 08/12/2015, the hospital provided the pharmacist's personnel file. The file did not contain documentation of the pharmacist's current license. There was no documentation of the completion of annual continuing education that is required to maintain state licensure.

2. The pharmacist's personnel file did not contain documentation of annual performance evaluation and competency verification.

3. On 08/13/2015, 08/17/2015 and again on 08/18/2015, the hospital was asked to provide pharmacy and therapeutics committee reports, all medication error reports and policies and procedures, adverse event reports and policies and procedures, and all pharmacy reports to the hospital medical executive and QAPI committees for 2014 and 2015.

The hospital provided a hospital-wide policy and procedure, dated 2002 and titled, "Medication Administration Errors, Adverse Drug Reactions and Incompatibilities." The policy had no documentation it was written based on national standards of practice.

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The policy referred to six other hospital policies for further information. Only one additional policy was provided. The policy, dated 02/01/2015 and titled, "Pharmacy Department Medication Errors" had no documentation it was based on national standards of practice regarding the investigation and root-cause analysis required for medication errors.

On 08/18/2015, the pharmacist was asked to provide documentation of medication errors and supporting reports, investigation, analysis and actions taken for medication errors and adverse events for 2014 and 2015. The only documentation provided was an event list for February 2014 and March 2014 that included three medication errors and two transfusion reactions.

No supporting documentation was provided to show the events were investigated, analyzed and acted upon. There was no supporting documentation provided for these events as required in the hospital's medication errors policies and procedures.

4. Other than reports about drug shortages and recalls, there were no comprehensive pharmacy reports to the medical executive committee and the QAPI committee for 2014 and 2015. The pharmacist had no documentation of reports to these committees regarding medication errors, adverse events and adverse drug reactions.

5. There was no documentation on the policies themselves, to show the medical executive committee reviewed and approved pharmacy policies and procedures. There was no

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documentation in the medical executive committee meeting minutes to show any oversight of the hospital's pharmacy services.

6. On 08/13/2015 at 2:00 p.m., a tour was conducted of the hospital's surgery department. During the tour, a metal rolling cabinet was observed in a store room. The cart was labeled for use in a malignant hyperthermia emergency. On the cabinet's bottom shelf were large bags of fluid labeled, "STERILE WATER FOR IRRIGATION." A surgery department RN stated those fluids were used to reconstitute Dantrolene, an intravenous medication needed during a malignant hyperthermia emergency. The Dantrolene label had a warning to instruct staff to reconstitute the medication with sterile water for injection only.

The RN was asked how the sterile water for irrigation was provided to the surgery department. She stated the fluid was provided by the pharmacist and that the staff was told this fluid could be used to reconstitute Dantrolene to be given IV. She could not recall how long the fluid had been on the emergency cart.

The label on the bag of irrigation fluid documented, "CONTRAINDICATIONS: NOT FOR INJECTION... WARNINGS: HYPOTONIC AND HEMOLYTIC... Dosage: irrigation. "

On 08/18/2015, the pharmacist was asked about the bags of sterile water for irrigation that were supplied on the surgery department malignant hyperthermia cart. He said he had heard about that issue and he had just replaced those bags with sterile water for injection.

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The hospital had no pharmacy policy that restricted the distribution of large bags of sterile water for irrigation to certain areas and for specific uses. There was no policy to prohibit its use for injection or infusion. The hospital had not identified the bags of sterile water for irrigation as a potentially dangerous "look alike, sound alike" product that could be accidentally used for injection or infusion.

The hospital had no policy to identify, document, respond and train staff on a "near miss" event such as this.

7. During the surgery department tour on 08/13/2015, the nursing staff was asked if the pharmacist periodically inspected the storage and administration of medications and biologicals in that department. She stated he did not. She stated the RN staff was responsible for oversight of these things in the department.

On 08/18/2015, the pharmacist was asked if he periodically toured the surgery department to inspect how medications and biologicals were stored and to check for expired medications or other anomalies with these products. He stated he did. He was asked to provide documentation of these inspections for 2014 and 2015.

The pharmacist provided documentation for January 2015 only. The forms documented the recovery room and "anesthesia" rounds were conducted by another pharmacy staff member. No deficiencies were identified according to these documents.

The pharmacist did not provide any other documentation of inspections of the other areas

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| A 490 | Continued From page 15<br>within the surgery department for 2014 or 2015.<br><br>8. On 08/18/2015, the pharmacist was asked to provide documentation of pharmacy QAPI indicators and QAPI activities and all reports to the hospital's QAPI committee. These documents were not provided. There was no documentation found in the QAPI committee meeting minutes that indicated medication errors, adverse reactions and other untoward medication administration events were reviewed. | A 490 | | |
| A 700 | 482.41 PHYSICAL ENVIRONMENT<br><br>The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, interview and document review the hospital failed to ensure:<br><br>a. the condition of the hospital was constructed, maintained and repaired to ensure the safety and health for patients and staff;<br><br>b. preventive maintenance, testing and repairs were completed in a timely manner for all hospital equipment; and<br><br>c. the hospital failed to develop and implement an emergency preparedness plan.<br><br>Findings:<br><br>1. On 08/11/2015, 08/12/2015, 08/13/2015, 08/17/2015 and 08/18/2015, OSDH surveyors | A 700 | | |

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toured and inspected the hospital's facilities with hospital leadership and staff. The following deficient practices were identified:

Surgery Department Design, Access and Traffic Flow

The surgery department had been modified from its original design. These changes were not submitted to OSDH for review and approval as required by state regulations. As a result of these unauthorized changes, the surgery department no longer conformed to the design standards and requirements needed to maintain proper infection control and safe surgical practices. The surgery department was not divided into two clearly designated areas - semi-restricted and restricted - defined by the physical activities performed in each area.

The hospital staff provided a floor plan they said reflected the current design and utilization of the surgery department. However, when the OSDH surveyors toured the surgery department, it was evident the floor plan no longer reflected the actual rooms and spaces. Doors had been added or removed, rooms had been re-purposed and instrument processing tasks, including high level disinfection were being done in an alcove in the semi-restricted corridor, rather than in the decontamination room of the surgery department. A small " satellite" decontamination room was found in the surgical central corridor. This room was identified on the floor plans as a soiled utility room. The room did not meet the design requirements for an instrument decontamination room.

The larger instrument decontamination room was

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only accessible to surgery staff through the sterile processing room or by traveling out of the surgery department and through a public corridor. This meant that the surgery staff carried contaminated surgical instruments through two clean surgical supply storage rooms, through the sterile processing room (a restricted area), through another storage room to finally reach the decontamination room which is a dirty restricted area. After leaving the dirty area of decontamination, the staff traveled back through the clean areas to reach the operating rooms.

The surgery department had no central control point to monitor the entrance of patients, personnel (authorized or unauthorized) and materials from the unrestricted areas into the semi-restricted areas. There were eight points of entry into the department. There was no way for the surgery staff to monitor who entered and exited the semi-restricted and restricted areas of the department.

The hospital incorrectly identified and labeled the entry corridor into the surgery department. The portion of the corridor beyond the first set of double doors should have been identified as semi-restricted. Instead, the hospital labeled a part of the corridor unrestricted and a part beyond a diagonal red line was identified as semi-restricted. The red line was used to identify the point between the unrestricted and the semi-restricted traffic areas. However a warming cabinet, a janitor's closet and a biohazard waste collection room (exclusive to the surgery department and required to be in the semi-restricted area), were instead located in the unrestricted portion of a corridor where persons in street clothes came into and out of the

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department. This meant that persons in scrub attire who were working in the surgery department had to pass persons in street clothes in the unrestricted portion of the corridor to gain access those working areas.

Because the surgery department did not have all the required rooms and spaces, and did not have the space for all the supplies and equipment needed for the scope of surgical services provided, the staff stored supplies and equipment (both sterile and non-sterile) in a cluttered and disorganized manner in every room in the department, even spilling out into the corridors.

The entry corridor to the surgery department was used to store a vacuum cleaner, a large stainless steel surgery table and a large biohazard waste collection bin. This corridor also held a rolling linen cart that contained the linens needed inside the operating rooms and in other areas of the surgery department. All of these items should be stored in appropriately dedicated rooms located inside the surgery department.

There was unrestricted access to the surgery department from another public corridor. An unlocked door from this public corridor led into an office that was directly open to the sterile processing room. There was no separation between the office (which should be considered a semi-restricted office within the surgery department and enclosed separately from other areas) and the restricted sterile processing room.

There was another unrestricted public corridor that led past the recovery room and directly into the central core of the operating rooms. There were double doors that separated the public

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corridor from the semi-restricted portion of the corridor, but the staff propped this door open at times. This allowed public traffic to travel past the surgery holding room, past the recovery room and up to a red line on the floor that marked where the unrestricted corridor stopped and the semi-restricted central surgery corridor began. This red line was placed immediately adjacent to the surgical scrub sinks. This allowed unmasked persons to be in close proximity to the surgical scrub sink when surgical hand scrubbing was performed. (Surgical hand scrubbing must be done by staff wearing a surgical mask.)

Temperature, Humidity, Air Exchanges, Filtration and Airflow

Surgical instrument decontamination, high-level disinfection, sterilization and all other areas of the surgery department did not maintain appropriate temperature, humidity, air exchanges, filtration and airflow as required by nationally accepted design requirements. Staff propped doors open or left doors open to control temperature and humidity. (Failure to follow design standards allow bacteria to thrive in higher temperatures. Relative humidity higher than those recommended can promote microbial growth and increase bioburden. The ventilation system should be designed and maintained so that airflow patterns will not allow air contaminants to enter clean areas. Air should flow from positive pressure to areas of negative pressure. Air under negative pressure should be exhausted to the outside via a non-recirculating system, AAMI, 2012).

A hospital form titled, "Sterile Processing Department ICP [Infection Control Professional]

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Survey Assessment," dated 06/15/2015, documented the instrument decontamination area, general surgery work areas, sterilization preparation and packaging, and sterile storage areas had humidity levels of 65%. (A range of 30-60% is acceptable, AAMI 2012 and AORN 2013.)

The form documented the "clean area" within the surgery department had a negative airflow from the public corridor outside of the surgery department. (The surgery department clean areas should maintain positive airflow relative to areas outside of the department, AAMI 2012 and AORN, 2013).

The form documented a portable fan was present in the sterile processing area. The form did not document what action was taken as a result of this finding. On 08/12/2015, a portable fan was observed sitting on the floor in the sterile processing room. The staff stated they used the fan to lower the room temperature and to provide ventilation. (Neither fixed nor portable fans should be permitted in any area of the sterile processing department, AAMI, 2012).

The biohazard waste collection room did not maintain negative airflow and was not exhausted to the outside.

Surgical Instrument Decontamination Room

The June 2015 Sterile Processing Department ICP Survey Assessment form documented the surgical instrument decontamination room should have a "three sink configuration for concurrent soaking, washing and rinsing [of surgical instruments]." At the time of the survey, the room

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was equipped with a two compartment sink that was intended for ware-washing in a food service department. This two compartment sink was not original to the room design and was installed blocking a Dutch door that led out into a public corridor. The two compartment sink was rusted and showed signs of oxidation and accumulation of mineral deposits. These conditions prevented adequate disinfection of the sinks. Plumbing pipes underneath the sink were not enclosed. The pipes were rusted and had green corrosion and growth of mold on them. There was evidence of chronic water leaks on the floor around the pipes.

The surgery instrument automated washer was not maintained and verified to be functioning adequately. There were records of repeated malfunctions with this piece of equipment. The hospital did not have a policy and procedure for validation and verification that the washer was effectively decontaminating surgical instruments. At the time of survey, the washer had thick mineral deposits inside the machine. The surgery staff did not have access to the manufacturer's instructions for the regular cleaning and maintenance of the washer. (Water hardness, pH and temperature can affect the effectiveness of enzyme cleaners and detergents, CDC, 2008 and AAMI, 2012).

The hospital documented in December 2014 the following, "Major concerns: [decontamination] washer cycle log counter is not working and unable to fix. This unit needs [to be] replaced ASAP. Currently looking for funding and options ... "

Also in December 2014, the hospital identified the

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following, "Decontamination [room] 75 degrees and high humidity..." An internal email, dated 12/19/2014, documented, "Some high priority issues ... the decon room is now warmer than it used to be with the new doors installed and closed. This is an issue and per infection control standards this should be the coolest room. It is the warmest and I know the humidity exceeds standards as well. I need a temp and humidity monitor for this room at some point so I can watch it closer ... "

At the time of survey, the room did not provide the proper temperature, humidity, negative airflow pressure, or proper clean air exchanges and filtration required for a decontamination room. (Decontamination rooms should have negative airflow pressure with ten air exchanges per hour and should be exhausted to the outdoors. Decontamination rooms should be temperature controlled between 60 and 65 degrees, AAMI, 2012).

The decontamination room had acoustical ceiling tiles throughout. The ceiling tile above the automated washer was water-stained and had evidence of black mold and mildew. There was a water leak stain running down the wall from the ceiling. (Work area ceilings should be constructed of materials that are not of a particulate or fiber-shedding composition. Ceilings in restricted areas such as decontamination rooms shall be monolithic, scrubbable, and capable of withstanding chemicals. Cracks or perforations in these ceilings are not allowed. All access openings in ceilings in restricted areas shall be gasketed, FGI, 2014).

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A ceiling vent over the decontamination work area was rusted and condensation was actively dripping from it onto the floor at the time of the survey. The floor throughout the room was rust-stained. Metal cabinetry in the room had signs of oxidation and accumulated mineral deposits. The room had wood shelving and peeling wallpaper. (The floors, walls, ceiling and work surfaces should be constructed of non-porous materials that will withstand frequent cleaning and wet conditions, AAMI, 2012).

The condition of the decontamination room (evidence of dust, debris, dirty equipment, clutter, disorganization) indicated the room was not adequately cleaned and disinfected on a daily basis and did not receive terminal cleaning or periodic deep cleaning. The walls were covered in wallpaper that could not be disinfected. Air return vents were dirty in this room.

The staff was not adequately trained to keep the decontamination room clean and disinfected. A household broom and dust pan (improper cleaning equipment for this room) were found in a corner of the room. A non-slip mat in front of the automated dishwasher had not been moved for cleaning beneath it. When it was lifted, there was dirt, grime, water stains and rust on the floor beneath the mat. The linoleum tiles in this room had been exposed to so much water that they were separating and the gaps between them collected dirt and debris. The decontamination room should have monolithic flooring with welded seams. (Terminal cleaning and disinfection of the perioperative environment decreases the number of pathogens, dust, and debris that is created during the day. A cleaning schedule for areas and equipment that should be cleaned on a daily,

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weekly or monthly basis should be established and enforced, AORN, 2013).

The staff was asked to provide a deep cleaning schedule for the decontamination room. This document was not provided.

Endoscope Decontamination Room

A small soiled utility room (a required room within a surgery department) had been converted into an endoscope decontamination room. As a result, the surgery department no longer had the required soiled utility room. When the room was re-purposed as an endoscope decontamination room, it fid not have the required features for a decontamination room.

The room did not provide the proper negative airflow pressure, or proper clean air exchanges and filtration. The door to this room remained open to the surgical central corridor at all times. The staff stated the room was too small and too hot to keep the door closed. (Decontamination rooms should have negative airflow pressure with ten air exchanges per hour and should be exhausted to the outdoors. Decontamination rooms should be temperature controlled between 60 and 65 degrees, AAMI, 2012).

The room had a double sink for decontamination of endoscopes. The room had no separate staff hand washing sink. The staff had to use the instrument sinks for regular hand washing. A paper towel dispenser was placed over the instrument sinks. There was no hand washing antibacterial soap available at the sinks. It could not be determined how the staff safely and effectively performed hand washing as required

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before gloving and after removing gloves. (Instruments should not be decontaminated in scrub or hand sinks. Cleaning soiled instruments in a scrub or hand sink can contaminate the sink and faucet, which also should be used for clean activities such as routine hand washing and surgical hand antisepsis. Likewise, hand washing should not be done in instrument decontamination sinks, AORN, 2013).

The room had no emergency eye wash station.

There was insufficient counter space in the room to adequately separate the dirty and clean parts of decontamination processes. The staff left towels on the counters between cleaning individual scopes and the towels remained there at the end of the day when all decontamination activities were finished. (Towels used in the decontamination of endoscopes are considered contaminated and should be discarded after each scope is processed.)

The staff used plastic syringes as a part of the scope decontamination process. These syringes were reused from day to day, rather than discarded and replaced after each use as directed by the manufacturer.

Supplies and clean linens were stored unprotected on open wood shelves in this room. These items should have been stored in enclosed cabinetry to protect from incidental contamination and splashes.

An electrical cord was strung from a piece of equipment, along the wall over the paper towel dispenser and over the sinks, across to the other side of the room.

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| A 700 | Continued From page 26<br><br>This room had acoustic ceiling tiles, flooring that was not monolithic, and a hole in the wall above its clock.<br><br>High Level Disinfection Processing<br><br>High level disinfection for endoscopes and other surgical equipment was not confined to the restricted area of the surgical instrument decontamination room. Instead, it was performed in an open alcove in the semi-restricted surgery corridor where staff and patients traveled past as they entered the surgery department.<br><br>This alcove could not provide the negative airflow pressure, or proper clean air exchanges and filtration required for a decontamination room. The alcove did not include a separate hand washing sink for staff. There was no hand washing antibacterial soap or paper towels located in this work area. (Staff are required to wash hands before donning gloves and when gloves are removed, AORN, 2013).<br><br>The room had no emergency eye wash station.<br><br>At the time of the survey, supplies and clean linens were stored on open shelves over the work area instead of within enclosed cabinetry that would protect from them incidental contamination and splashes. One shelf held items still in their shipping boxes. (To eliminate the risk of introducing contaminants that may be present on external shipping cartons, these cartons should not be permitted in clean/sterile storage areas, AAMI, 2012).<br><br>Items were stacked on high shelves within a few | A 700 | | |

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inches of the acoustic ceiling tiles. One open shelf held a bottle of chemical test strips that was left open. (Exposure to air and light degrades these test strips and makes them ineffective. These strips were to be used to test the efficacy of the high level disinfectant solution.)

A dirty two compartment sink was found in this alcove that some staff said was used to wash surgical instruments before they were put into the chemical processors. An enzymatic instrument cleaning solution was found at the sink. Some staff said the sink was used to rinse some items when they came out of the processors. Other staff said the sink was used just for hand washing. Clean items were stored along the parameter of the sink within the splash zone.

The processing equipment filters frequently leaked when they were changed, so the staff placed a plastic trash can beneath one filter to catch water leaking out and a five gallon plastic container under another filter to catch water leaks there.

One staff person stated a micron filter for the processor was changed every month. The manufacturer instructions obtained by the surveyors documented the filter should be changed every 90 days. Changing the filters more frequently is indicative of a problem that should be diagnosed. A log sheet for the equipment documented multiple cycle failures and multiple diagnostic test failures. There was no documentation of actions taken in response to these failures.

A large metal multi-shelf rack was found in this alcove. The rack was rusted. The rack blocked

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access to the enclosure for the isolated grounding panels located inside a closet within this alcove. The rack held multiple plastic tubs the staff said were used to carry dirty endoscopes to the processors and to then carry them back to the storage cabinet located in one of the operating rooms. It could not be determined which of the plastic tubs were considered "clean" and which tubs were considered "dirty." One staff member stated the same plastic tub used to carry the dirty endoscope to the decontamination room was also used to carry the now clean endoscope to the chemical processor and then back to the operating room. She was asked to repeat this information. When she did, she then stated she realized what the problem was with this practice.

A fifty gallon trash can with no lid was found in this area.

Sterile Processing Room

The sterile processing room had evidence of excessive heat and humidity levels. There was black mold on the acoustic ceiling tiles above the steam sterilizer. A portable de-humidifier was placed on a wood shelf in the sterile processing room. The water run-off tubing was strung into the staff hand washing sink to drain. Doors were propped open in sterile processing to help control temperature and humidity. (The sterile processing room is a restricted area that should be provided with positive airflow, ten air exchanges per hour and controlled temperatures between 68 to 73 degrees, AAMI, 2012).

The hospital's safety committee meeting minutes dated, 07/01/2015, documented, "... Humidity issues in O.R., Engineering has not had the

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capability of monitoring humidity values and was dependent on department monitoring. Portable humidifier was purchased to assist with the current issue... He states the use of recently installed dehumidifiers blowing hot air has improved the humidity problems in OR and SP [sterile processing], but increased the room temperature... new equipment is cost prohibitive, but other options will be considered to alleviate the air balancing problem in sterile processing. There is discussion on possible installation of another door on the other side office that would help with airflow... "

A small two shelf rolling cart was found in the sterile processing department. On the top shelf, the staff wrapped instrument sets for sterilization. On the bottom shelf, the staff stacked two large sets of sterilized instruments on top of each other. This lower shelf was three inches from the floor. (Sterile and non-sterile items should be kept separate from each other. Sterile items should be stored at least 8 to 10 inches above the floor. Sterilized instrument sets should not be stacked, AAMI, 2012).

A small room open to the sterilizer room was used to wrap clean instruments after they were passed through the automated washer. The room was too small for this purpose and had no table or working counter space large enough for instrument set wrapping and other sterile packaging functions. The room was extremely cluttered. Notebooks, binders, papers and other items not related to instrument packaging were scattered among surgical equipment that was clean and ready to be packed for sterilization. On 08/12/2015, a portable fan was observed on the floor of this room pointing in the direction of clean

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surgical instruments. (A blowing fan placed on the floor would likely transfer microorganisms from the floor to clean surfaces.)

In December 2014, the hospital identified the following through it's own surveillance document, "...Rust build-up on sterilizer rack. This loose material prevents cleaning and sterilizing of the rack..." The hospital identified the following during surveillance in June 2015, "SPD [sterile processing department] humidity 65%... clean area negative to corridor by elevators,... one fan present, not in use... sterilizer racks still have issues with loose rust particles..." The hospital had taken no actions on these findings and the conditions were still present at the time of survey.

Metal cabinetry in this room was rusted. The room had a cork bulletin board with loose papers tacked to it. The walls were covered in wall paper. Clean surgical instruments were placed on dirty and dusty countertops among papers, plastic wrappers, dirty towels, spray bottles with a clear liquid the staff said was alcohol, empty spray bottles, tape dispensers, bubble wrap and sterile supplies.

There were no clear working surfaces in this room. The room had accumulated so much extraneous material that it was evident it was not cleaned periodically through the day, was not terminally cleaned at the end of the day and had not received any type of deep cleaning. When the staff was asked about the deep cleaning of the department, they were not familiar with the term and did not understand what deep cleaning involved.

Sterile Supply Storage

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Sterile supplies were stored in random, uncontrolled areas throughout the entire department, including traffic corridors. Sterile supplies in the corridors were stored on uncovered carts or on open shelves. Sterile supplies in the corridors were also stored with equipment. Sterile packages were forced into bins and were crushed, bent and compressed in a way likely to compromise the integrity of the packaging. Sterile supplies were stored indiscriminately with non-sterile supplies in all areas of the department.

A sterile supply room located between operating rooms four and five had wood paneling on the walls. The staff called this "the trailer park room." (Wood paneling surfaces cannot be disinfected.) Sterile instrument sets were stored stacked on top of each other on shelves touching walls and within a few inches of the acoustic ceiling tiles. The top shelf closest to the ceiling was heavily covered in dust and debris. Sterile instrument sets were stored on this top shelf.

In December 2013, the hospital's infection control committee meeting minutes documented, " GMH facility rounds reports reviewed for OR, sterile processing... supplies on floor and some items stacked too high on storage shelves in OR... "

The main sterile supply storage room was open to the sterilizer room and proper temperature and humidity could not be maintained in this area. There was evidence of humidity damage to the walls in this room. Supplies were stored on wood shelves. Sterile supplies were stored with non-sterile supplies. Surgical equipment was also stored in this room.

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Operating Room Number One

Endoscopy procedures were performed in this operating room. The staff was asked about endoscope processing and storage. The staff stated that when the endoscopes were taken out of the processors after disinfection, they were transported in contaminated plastic tubs back into this operating room where the endoscope storage cabinet was located. (The staff stated this operating room was used for other types of surgeries and was not limited to endoscopy.) Near the scope storage cabinet, the staff stated they used compressed air from a wall outlet to blow out water that remained inside the channels of the endoscopes. The water was blown out onto the operating room floor.

Because of the slip and fall hazard, the staff placed a non-slip mat on the operating room floor immediately in front of the endoscope storage cabinet. After blowing out the water, the staff stated they used a spray bottle of alcohol to spray the outside and inside the ports of the scopes. The staff stated this was done to help clean the scopes. The staff did not flush the endoscope internal channels with alcohol after removing the water. (Removing excess water from the endoscope channels and flushing with alcohol is a part of the endoscope disinfection process and this should not be performed in an operating room, CDC 2008 and ASGE, 2011).

At the time of the tour, the staff was asked if this operating room had been terminally cleaned for the day. The staff stated it had been. It appeared the non-slip mat had not removed and cleaned, and the floor beneath the mat was still

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dirty. A toothpick was found on the operating room floor. The floor was dirty overall and attention had not been paid to corners and the wheels on moveable equipment. The staff stated the room was difficult to clean because it was "old."

Multiple surfaces were cluttered and had not been recently damp-dusted. Dust and debris was found on many surfaces inside the operating room. (Floors should be wet-vacuumed with an EPA-registered disinfectant after scheduled cases are completed. All horizontal surfaces should be damp-dusted and disinfected as a part of the terminal cleaning process, AORN, 2013)

Operating Room Number Two

This operating room was decommissioned and was being used to store surgery equipment. This room was dirty and in disrepair. An open pipe protruded from the middle of the floor. There were open holes in the walls with exposed electrical wires. It could not be determined if the surgical equipment stored in this room had been cleaned because so many surfaces were dusty, had grime and evidence of dried splashes. The staff stated there was useable and broken equipment stored together in this room.

There were rolling carts with white towels on them that were dirty. One rolling cart had a plastic tub with a broken lid. The tub was labeled "biohazard." The tub was lined with a towel and on top of the towel was a cystoscope. The staff was asked if the cystoscope was clean and ready for use. The staff stated they were "not sure." The staff was asked if this was proper storage for a cystoscope. No reply was given.

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| A 700 | Continued From page 34<br><br>There was a rusted metal cabinet that held sterile supplies. Some of the sterile supply packages (urology stents) were yellow and brittle. They were dated as packaged by the manufacturer in 1997.<br><br>The room held a 50 gallon trash can. The outside of the trash can was dirty with grime and dried splashes.<br><br>There were fabric curtains hanging on the inside of the operating room doors. The staff said these curtains were put in place to provide extra patient privacy in this room. (Health care textiles, e.g., privacy curtains, may become contaminated by bacteria and fungi and microbes can survive on textiles for extended periods. Contaminated textiles can contaminate the environment, AORN, 2013).<br><br>Sub-Sterile Room between Operating Rooms 3 and 4<br><br>The door from this room to the surgical core was open at all times. A large steam flash sterilizer was located in the room. The sterilizer was found to be operational because it was warm at the time of survey. There was a large open hole in the floor beside the sterilizer. A pipe ran from the sterilizer to the hole in the floor. There was evidence of chronic water leaks in and around this pipe. Fungus and black mold was growing in and around this hole and on the surrounding floor. The sheetrock in this room was peeling. The internal racks to the sterilizer were placed on the floor and propped up against a wall. This sub-sterile room had doors that opened into the two adjacent operating rooms. | A 700 | | |

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Surgery Manager's Office

This room opened to the surgery semi-restricted corridor and also opened to another office that opened directly into the sterile processing area. There was stained and ripped carpet in this room. Some rips were patched with silver duct tape. One section of carpet was removed and the cement floor below was exposed. A wall had evidence of water damage. The room was cluttered and was dusty and dirty.

General Condition of the Surgery Department

The following environmental conditions were found throughout the surgery department:

Surgery equipment with wheels in multiple areas within the department showed evidence they were not routinely cleaned. The wheels had a built up of dirt, dust and grime. Some wheels had old suture and hair tangled in them.

There were multiple pieces of metal equipment throughout the surgery department that were severely damaged by rust. (Damaged and corroded metal surfaces cannot be adequately disinfected, AAMI, 2012).

Ceramic tiles on the floors and on the walls were chipped, cracked or broken. Multiple other types of work surfaces, such as Formica and plastics, were damaged and no longer intact and could not be adequately disinfected. (Non-intact environmental surfaces cannot be adequately cleaned and disinfected, AORN, 2013).

There were numerous wood surfaces in various

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locations in the department that were unfinished, unsealed or damaged. Some wood surfaces were covered with a paint that could not withstand the strong disinfectants required in the surgery department. The surgery staff said these surfaces were "dry-dusted." (Porous surfaces cannot be adequately cleaned and disinfected, AORN, 2013).

Painted corkboard was used to hang various surgery items throughout the department. Cork bulletin boards were found in sterile processing and in the decontamination rooms. (Corkboard is a shedding material that contaminates the surgical environment, AAMI, 2012).

The surgery core corridor had a long, elevated crack in the flooring that ran nearly the entire length of the department. (Non-intact floors allow for the accumulation of dust and microorganisms, AAMI, 2012).

Thesurgery department contained upholstered furniture in various rooms and spaces, including the area within the surgery core identified as "reception." There were chairs in other areas of the surgery department with torn plastic coverings that allowed the inside foam to be exposed. (Fabrics and upholstery foam collect and retain environmental contaminants that cannot be readily disinfected, AAMI, 2012).

Acoustic ceiling tiles were missing over the surgical scrub sink and the attic area was exposed. Other acoustic ceiling tiles in the department were water damaged, had mold and mildew, and had not been replaced. There were acoustic ceiling tiles that were bowed and no longer fit securely in place.

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Plastic light covers in the ceilings showed evidence of old water leaks where water had pooled in them.

Baseboards and various trim pieces were missing, broken or loose in multiple places throughout the department. Where baseboards were missing, the underlying adhesive remained on the wall and collected dust, dirt and debris.

Plastic case carts were used to hold sterile supplies pulled for individual surgery cases. These carts were inadequately cleaned inside and outside. There was evidence of dirt and grime build-up that could not be removed because the plastic surfaces were not smooth.

A staff restroom opened directly into the semi-restricted surgery corridor. (Restrooms should be located within the staff lockers and breakroom areas and not in the semi-restricted corridor.) This toilet room did not have adequate negative airflow and ventilation and the door remained open when not in use. (Restrooms should have negative airflow with ten air exchanges per hour and should be exhausted outdoors, AAMI, 2012).

Insect spray was used in the surgery department. (Insects and rodents can carry pathogens that cause disease, AORN, 2013).

The surgery staff was asked if the department was ever deep cleaned to include stripping the floors, damp mopping and disinfecting all walls and ceilings in all areas of the surgery department. They stated it was not.

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| A 700 | Continued From page 38<br>Hospital-wide<br><br>Throughout every day of the survey, the hospital had a pervasive odor that was similar to sewer gas. An open sewer pipe was found on the roof near the fresh air intakes. At other times, the hospital had a smell similar to mold and mildew. Different areas of the hospital were described by staff and patients to be "warm, damp and stuffy."<br><br>2. Routine inspections and preventive maintenance was not performed on all hospital equipment.<br><br>3. The hospital had no documentation of a comprehensive emergency preparedness plan. Other than fire drills, the hospital had not conducted or documented any other types of emergency drills. There was no documentation to show how the hospital participated in the state-wide emergency preparedness system.<br><br>See Life Safety Code survey for additional findings applicable to the hospital's physical environment. | A 700 | | |
| A 747 | 482.42 INFECTION CONTROL<br><br>The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, interview and document review, the hospital failed to: | A 747 | | |

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a. maintain temperature, humidity, ventilation and filtration in the surgery department to inhibit the growth and spread of pathogens;

b. adhere to national standards of practice and manufacturers' guidelines for surgical instrument decontamination, high level disinfection and sterilization;

c. maintain aseptic conditions in all parts of the surgery department;

d. store surgical supplies in a manner to ensure integrity and sterility;

e. provide hand washing facilities as required for staff in the surgery department;

f. provide emergency eye wash stations as required for staff in the surgery department;

g. train and verify staff competency on the infection control practices related to their job duties;

h. ensure comprehensive infection control surveillance, reporting and corrective actions for all areas of the hospital; and

i. the hospital failed thoroughly investigate potential causes of surgical site infections.

Findings:

An OSDH survey conducted on 05/23/2015 identified that the hospital infection control program did not provide adequate surveillance of surgery department and of sterilization practices.

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1. A the time of survey, environmental controls were not maintained in the surgery department for air exchanges, exhaust ventilation, temperature and humidity as required for the various areas within the department. Excessive temperatures and humidity levels were present. There was improper exhaust ventilation, airflow, air exchanges and filtration in all rooms and spaces.

A hospital form titled, "Sterile Processing Department ICP [Infection Control Professional] Survey Assessment," dated 06/15/2015, documented the "clean area" within the surgery department had a negative airflow from the public corridor outside of the surgery department. (The ventilation system should be designed so that airflow patterns will not allow air contaminants to enter clean areas. Air should flow from areas of positive pressure to areas of negative pressure. Air from rooms or areas under negative pressure should be exhausted to the outside via a non-recirculating system. Each functional area has its own requirements for airflow, number of air exchanges and exhaust AAMI, 2012).

The form also documented a portable fan was present in the sterile processing area. The form did not document what action was taken as a result of this finding. A portable fan was found sitting on the floor in the sterile processing room at the time of the survey. The staff stated they used the fan to lower the room temperature and to provide ventilation. (Neither fixed nor portable fans should be permitted in any area of the sterile processing department AAMI, 2012).

Humidity damage was present in the surgery department on ceiling tiles and walls. There were

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chronic water leaks and around plumbing fixtures. There was evidence of mold, mildew and fungus actively growing on ceiling tiles and around plumbing fixtures in various areas. (Relative humidity higher than those recommended can promote microbial growth and increase bioburden AAMI, 2012).

A hospital form titled, "Sterile Processing Department ICP [Infection Control Professional] Survey Assessment," dated 06/15/2015, documented the instrument decontamination area, general surgery work areas, sterilization preparation and packaging, and sterile storage areas had humidity levels of 65%. (A range of 30-60% is acceptable, AAMI 2012 and AORN 2013.)

In December 2014, the hospital identified the following, "... Decontamination [room] 75 degrees and high humidity... " An internal email, dated 12/19/2014, documented, "... Some high priority issues... the decon room is now warmer than it used to be with the new doors installed and closed. This is an issue and per infection control standards this should be the coolest room. It is the warmest and I know the humidity exceeds standards as well..."
(Bacteria thrive at high temperatures; cool temperatures in the decontamination area might help minimize bioburden AAMI, 2012).

Prior to the survey, the hospital identified problems in these conditions. Inadequate and sometimes inappropriate actions were taken in response. Some conditions were not identified and acted upon.

2. Nationally accepted standards of practice were

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not followed for surgical instrument decontamination, high level disinfection and sterilization. The hospital did not have adequate policies and procedures, based on nationally accepted guidelines, for all the tasks in these areas.

The hospital did not provide the staff with the manufacturers' guidelines for surgical instrument processing and sterilization. The hospital did not have instructions specific to each type of surgical instrument and therefore it could not be verified the hospital processed instruments correctly.

The hospital also did not provide the staff with the manufacturers' recommendations for the operation of the equipment critical to these processes. (The written manufacturers' instructions for use for each device should always be followed. This information should be kept on file and periodically reviewed for updates. If there are no specific written instructions for use, then the manufacturer should be contacted directly to provide a documented method. To ensure patient safety, a reusable device must be capable of being thoroughly cleaned and sterilized. The manufacturers' written instructions for use are the basis for the department's policies and procedures and must be kept up to date, AAMI, 2012).

The following failures were identified in surgical instrument decontamination:

~The hospital did not provide adequate physical space and the correct facility features to separate "dirty" and "clean" processes in the decontamination areas. When the surveyors entered the decontamination areas, it was not

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clear where the clean and dirty areas were. (Separating "clean" and "dirty" areas limits environmental contamination and the potential for bioburden on devices to be sterilized. Adherence to functional design recommendations helps contain potential contaminants within a particular portion of the decontamination area and thus helps prevent cross-contamination or recontamination, AAMI, 2012).

~A nylon toilet brush was found at the instrument decontamination sinks. (Brushes and other cleaning implements intended for use on medical devices should be used. They should either be single-use, disposable items or, if reusable, be decontaminated at least daily. Microorganisms, patient tissue, blood and lubricants on brushes and other cleaning implements could be transmitted from one device to the next during cleaning. In addition, accumulated microorganisms, patient blood and patient tissue on cleaning implements pose potential health risks to personnel, AAMI, 2012)

~The hospital relied on a malfunctioning automated instrument washer for surgical instrument cleaning in the decontamination room. The washer showed heavy mineral deposits inside the machine. Other processing equipment showed evidence of mineralization and oxidizing. (Water hardness, pH and temperature can affect the effectiveness of enzyme cleaners and detergents CDC, 2008 and AAMI, 2012). The hospital had no method or policy and procedure to verify the efficacy of the washer.

~If the staff performed manual instrument washing, it was not performed with a three sink method as required according to national

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standards and according to the hospital's own surveillance requirements.

~The hospital did not require the staff to document instrument cleaning to include all of the following: the date and time, the instruments cleaned, the method of cleaning, the number or identifier of mechanical decontaminator, name of person performing the cleaning, the name of the chemical and the lot numbers, records of testing the equipment and the results, and the disposition of defective equipment. (Most sterilization failures result from inadequate cleaning of the instruments before sterilization AORN, 2013).

The following failures were identified in instrument sterilization:

~The hospital did not provide a method for inspecting for the cleanliness of instruments such as magnification and ancillary lighting.

~Clean instruments were wrapped and packaged for sterilization in a room that was dirty and did not provide the space and facilities necessary to prevent contamination during these tasks.

~The hospital's infection control activities calendar for April and June 2015 documented that observations would be made of surgical instrument cleaning. There was no documentation of these observations and no documentation of actions taken as a result of the findings.

~ The hospital staff was asked to provide documentation of immediate use steam sterilization events. The staff stated there were some times when IUSS was performed, but they

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did not keep a running log of those occurrences. The hospital had no method to readily identify when IUSS was performed and what patient received an IUSS item during surgery. The staff stated they had to look through every day's records to pick out the IUSS event.

The staff was asked to provide any documentation of IUSS. None was provided. (Documentation of cycle information and monitoring results should be maintained in a log as a means for tracking items that are processed using IUSS to individual patients and for quality monitoring AORN, 2013).

~A sub-sterile room between two operating rooms was equipped with a steam sterilizer for IUSS. The staff stated they no longer used this sterilizer, but at the time of the survey, the unit had not been decommissioned and it was still active (warm) and ready for use. There was an open hole in the floor next to this sterilizer for a pipe that was connected to the machine. Black and green mold and tall fungus was growing in and around this hole. Also on the floor were two racks that had been taken out of the sterilizer and propped against the wall. (Fungi such as Aspergillus are an example of pathogens that can be released and dispersed as a result of damage to a water pipe AORN, 2013).

~The hospital did not require complete documentation of normal sterilization cycles to include the type of sterilization method (gravity displacement, dynamic air removal, ethylene oxide, hydrogen peroxide gas plasma, hydrogen peroxide vapor, ozone or dry heat). The staff could not articulate the type of sterilization method they used.

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Sterilization records also did not include the specifics of the sterilization cycles to include the duration of the exposure time and temperature phase of the cycle. The staff said this information was kept elsewhere. The surgery department did not keep adequate records of the contents of each sterilization load. Plastic peel packs that the staff stated contained various surgical instruments were documented on the sterilization records as "papers." There was no record of what specific surgical instruments were contained in the peel packs. (Complete and accurate documentation ensures that the sterilization process is monitored as it is occurring, ensures that the cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether a recall is necessary, should evidence subsequent to lot release, such as a positive biological indicator test or non-responsive chemical indicator, suggest sterility problems. Knowing the contents of the lot or load enables personnel to identify the medical devices to be recalled. In addition, complete documentation provides evidence of the department's quality control program AAMI, 2012).

~High level disinfection records for endoscopes were incomplete. The pass/fail documentation for the disinfection cycle was not included on the document that recorded the patient name and the number of the endoscope used for the patient. Other records found near the high level disinfectant processors documented multiple failures with the machine cycles. There was no documentation of actions taken for these failures.

A hospital policy titled, "Infection Control - Applies

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to the Operating Room," documented incomplete and incorrect information on how to process endoscopes when the automated machines were not working. There was no documentation within the policy to show it was based on the high level disinfectant manufacturer or the endoscope manufacturer's recommendations for manual cleaning processes.

On 08/13/2015 at 2:30 p.m., Staff Q described the process of HLD for the endoscopes as follows:

For the bedside cleaning process, the staff stated a mixture of enzymatic cleaner and water was poured in a small plastic bowl. (Enzymatic cleaner is used to remove protein from surgical instruments AORN 2013). This mixture would be used for multiple patients throughout the day. Staff Q stated she refilled the same bowl as needed. The mixture was not discarded and the bowl was not disinfected between patients.

Following bedside cleaning, the endoscope was transported in a covered plastic tub on a wheeled cart from OR #1, through the semi-restricted corridor, to the endoscope decontamination room. The endoscope was pre-cleaned and placed back into the original now "dirty" plastic tub. None of the staff who described this process stated the plastic tub was disinfected after a dirty endoscope had been placed in it.

Next, the plastic tub with the now re-contaminated endoscope was taken from the decontamination room, back through the semi-restricted corridor, to the open alcove where high level disinfection took place.

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When the endoscope was removed from the HLD processor, the staff stated they sprayed five "squirts" of alcohol into the air and suction ports. This practice did not follow manufacturer's guidelines as the endoscope channels were not filled with alcohol in order to act as a drying agent. (Unfiltered tap water that remains in the channels has the potential to re-contaminate the endoscope with waterborne microorganisms AORN, 2013).

In the final step, the staff stated the endoscope was hung vertically in a closed cabinet. Although the staff stated the scopes were stored hanging with the electrical caps removed, a scope was observed hanging with the cap still attached. (Removing electrical caps allows air to dry any remaining moisture on the electrical connectors ASGE, 2011).

In the operating room where endoscopy was performed, the surveyors observed an endoscope irrigator extension tubing in place and ready for use. The staff stated the hospital's practice was to use the extension tubing for multiple patients throughout the day. The manufacturer's guidelines documented the tubing was a single use item for one patient and the tubing should not be reused or reprocessed.

During the survey, a single use disposable surgical hand scrub brush was found at the sink next to the endoscope processors. The staff stated they used it to clean the sinks and counters. This item is not an environmental cleaning implement.

The hospital's radiology policy for high level disinfection of equipment and ultrasound probes

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was approved by the infection control committee on June 25, 2015. The policy was not based on the probe's manufacturer's guidelines nor the high level disinfectant manufacturer's guidelines. The hospital did not have these materials available for review.

The policy had no provision for monitoring the temperature of the high level disinfectant solution for the duration of the disinfection process. The high level disinfection logs did not document the time the item went into the solution and the time it was taken out. It could not be determined the hospital performed high level disinfection effectively. The hospital had no quality process verification for this task.

The hospital's materials manager stated the hospital sent single-use surgical instruments to a contractor for reprocessing. The hospital did not ensure the contractor had validation and approval from the FDA for reprocessing this surgical instrument. The hospital obtained this information after prompted by the surveyors.

3. The hospital did not maintain a functional workflow in the following order, from potentially high contamination areas to clean areas:

decontamination area
preparation and packaging
sterilization processing
sterile storage
clean distribution

The hospital could not establish appropriate traffic patterns to prevent potential contamination because of the design and locations of the various rooms within the surgery department.

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Clean and dirty processes crossed back and forth and did not follow a dirty to clean flow.

All areas of the surgery department were not routinely cleaned according to accepted standards. Operating rooms that were said to be terminally cleaned at the end of the day, appeared as though they were not routinely cleaned throughout the day between surgery cases. Other areas within the department (decontamination, instrument wrapping, sterile storage) were so cluttered they could not be adequately cleaned periodically throughout the day.

These areas were not terminally cleaned or deep cleaned. (Terminal cleaning is performed at the completion of the daily surgery schedule and includes but is not limited to: surgical lights, and external tracks, fixed and mounted equipment, all furniture including wheels, and casters, handles of cabinets and push plates, ventilation faceplates, all horizontal surfaces, the entire floor, kick buckets and scrubs sinks AORN, 2013)

The staff could not articulate what environmental cleaning products they used and how they should be used. The infection control professional did not verify the cleaning activities in this department. He stated he was uncertain as to what specific disinfectants the staff used.

The hospital provided housekeeping policies and procedures for the surgery department and other patient care areas of the hospital. A hospital policy for cleaning the surgery department instructed staff to clean some areas with alcohol. (Alcohol is not an EPA registered disinfectant and should not be used to clean surfaces. In addition,

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alcohol is a flammable antiseptic that must be used with caution in the surgical setting AORN, 2013).

None of the policies instructed staff on how the disinfectant agent should be applied (saturation) and how long a surface should remain wet for the disinfectant to be effective, or if the surfaces required rinsing after disinfection. Many of the policies instructed staff to use a spray bottle method of application that is contrary to national infection control and surgery standards of practice for effective disinfection. (Cleaning and disinfection methods that produce mist, aerosols, or dust, e.g., spray bottles containing disinfectant, should not be used AORN, 2013).

The surgery department was composed of materials that could not be adequately cleaned and disinfected to include unfinished and damaged wood, wood paneling, corkboard, acoustic tiles, plastic surfaces that were not smooth, chipped and broken surface materials, non-monolithic floor tiles, wall paper and fabrics.

The hospital's infection control activities calendar for June 2015 documented observations of operating room procedure and suite cleaning would be conducted. A hospital document titled, "OR Observation Checklist" and dated 06/15/2015, documented the OR was not in good repair due to "cracked tile issues." Otherwise, the checklist documented the surgery department was "compliant" with standards for the surgery environment.

4. Sterile supplies were stored in random, uncontrolled areas throughout the entire department including traffic corridors. Sterile

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supplies in the corridors were stored on uncovered carts or on open shelves. Sterile supplies in the corridors were also stored with equipment.

Sterile packages were forced into bins and were crushed, bent and compressed in a way likely to compromise the integrity of the packaging. Sterile supplies were stored indiscriminately with non-sterile supplies in all areas of the department.

Sterile instrument sets were stored stacked on top of each other on shelves touching walls and within a few inches of the acoustic ceiling tiles. The top shelf closest to the ceiling was heavily covered in dust and debris. Sterile instrument sets were stored on this shelf.

In December 2013, the hospital's infection control committee meeting minutes documented, "GMH facility rounds reports reviewed for OR, sterile processing... supplies on floor and some items stacked too high on storage shelves in OR... "

The hospital did not provide, or did not enforce the use of a breakout area where surgical supplies could be removed from the external shipping cartons before they came into the surgery department. At the time of the survey, shipping boxes were found inside the surgery department. These shipping boxes were found stored with unpacked sterile supplies.

5. The hospital did not provide hand washing facilities as needed in the decontamination rooms and in the high level disinfection processing area. (Hand hygiene facilities should be conveniently located in or near all areas where instruments

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and other devices are decontaminated and prepared for sterilization AAMI, 2012).

6. The hospital did not provide emergency eye wash stations for staff in the decontamination and high level disinfection areas. (Emergency eye wash equipment should be readily accessible in order to provide first aid to employees exposed to injurious chemicals and materials. The availability of eye wash units for immediate emergency use is required by OSHA AAMI, 2012).

7. The staff responsible for instrument decontamination and sterile processing did not have documentation of initial education and competency validation on procedures, chemicals used, equipment, instruments and supplies related to these tasks. A review of the training files did not show evidence the staff were specifically trained on the essential functions of their jobs to include:

~decontamination methods specific to the specialized instruments used in the department,
~selection of instrument cleaning agents and cleaning methods,
~proper application of cleaning agents, including specific applications, dilution and special precautions,
~preparation of instruments and the use of equipment for sterilization,
~validation for cleaning and sterilization, and
~record-keeping.

The files had no documentation of training and skills competency verification for environmental cleaning of the surgery department.

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There was no documentation of skills competency verification from someone trained and experienced to do so.

On 08/13/2015, the administrator was asked if he thought the surgery staff were performing according to accepted standards of practice. He stated he assumed they were because most of them had been working in that department for many years. He was asked if he had toured the surgery department. He stated he had not.

8. A review of documentation provided by the hospital for infection control surveillance activities indicated that routine instrument decontamination, high level disinfection and sterilization practices were not evaluated for performance according national standards of practice.

The VP of Patient Care Services was asked if the surgery department had access to national standards of practice reference materials. She stated they did have that information. She was asked to provide those materials for review. None were provided.

9. The hospital infection control professional was asked to provide data regarding surgical site infections (SSI). The data provided indicated there were thirteen SSI between May 2014 and May 2015. The details of those infections were as follows:

Patient #1 had an exploratory laparotomy performed in May 2014. The patient remained hospitalized after the surgery. On post-operative day eight and nine, the patient's white blood cell count began to increase, indicating an infection.

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The surgical incision was noted to be red. Purulent material was drained from the incision and cultured. The culture was positive for Enterococcus faecalis.

Patient #2 had a laparoscopic cholecystectomy and laparoscopic appendectomy in May 2014. The patient was seen in the physician's office for complaints of incisional redness, pain, skin warm to the touch and fever. The physician opened the wound and purulent fluid "leaked out." The fluid was cultured. It was positive for Streptococcus anginosus group.

Patient #3 had an open appendectomy performed in May 2014. The patient was seen in the physician's office for complaints of redness and tenderness at the incision site. The incision was opened and a "foul-smelling " purulent material was cultured. It was positive for Basteroides fragilis.

Patient #4 had a laparoscopic then open hysterectomy in May 2014. The patient was seen in the physician's office for complaints of fever, pain and incisional redness. The physician removed sutures and explored the incision with a sterile swab. Purulent drainage was expressed and cultured. The culture was positive for Escherichia coli, Methicillin resistant staphylococcus aureus, and Streptococcus dysgalactiae.

Patient #5 had a laparoscopic hysterectomy performed in June 2014. The patient was seen in the physician's office for complaints of incisional drainage. Purulent drainage from the incision was cultured. It was positive for Staphylococcus aureus and Streptococcus agalactiae.

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Patient #6 had a laparoscopic cholecystectomy in June 2014. The patient's incision became swollen and red. The wound was cultured. It was positive for Staphylococcus aureus and Klebsiella pneumoniae.

Patient #7 had a total abdominal hysterectomy in June 2014. The patient had redness, swelling and green discharge from the incision. No culture was taken. The infection control professional determined this met the criteria for a SSI.

Patient #8 had a Cesarean section in August 2014. The patient was seen for a partially open incision. The patient seen in the clinic three times for wound complaints. On the third visit, the patient complained of foul odor from the incision. The wound was cultured and the patient was referred to the wound care clinic. The culture was positive for Enterococcus faecalis, Klebsiella Pneumoniae and Group G Streptococcus.

Patient #9 had a laparoscopic vaginal hysterectomy in October 2014. The patient's surgical incisions tested positive for E. coli, Staphylococcus aureus and Streptococcus agalactiae (Group B).

Patient #10 had a laparoscopic cholecystectomy in December 2014. The patient had signs and symptoms of an SSI. The patient was taken to surgery for wound incision and debridement. The wound was cultured. It was positive for E. coli. Later, the patient was gain seen for complaints of incisional pain, redness and pus. The wound was again cultured. The wound tested positive for MRSA and Streptococcus agalactiae (Group B).

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| A 747 | Continued From page 57<br><br>Patient #11 had an appendectomy in February 2015. During the post-op visit the wound was described as red, open and a small amount of pus was present with no odor. The wound was cultured. The wound tested positive for Streptococcus viridians.<br><br>Patient #12 had incision and drainage of an abdominal surgical incision infection twice in February 2015. The wound tested positive for Staphylococcus lugdunensis.<br><br>Patient #13 had a laparoscopic cholecystectomy in April 2015. The patient was found to have an abdominal abscess on a radiological exam. The abscess was drained and the fluid was sent to the laboratory for testing. The fluid tested positive for Enterococcus faecalis.<br><br>On 08/17/2015 at 2:45 p.m., the infection control professional provided the surveyors with additional SSI data for 2015 as follows:<br><br>May 2015- One SSI related to prosthetic joint infection/hip prosthesis<br><br>June 2015- One SSI with no details provided<br><br>July 2015- One SSI with no details provided<br><br>The infection control committee did not thoroughly investigate surgical site infections to rule out the following potential causes that could be related to surgical services:<br><br>~staff carriers of group A B-hemolytic Streptococcus<br>~improper use of surgical masks | A 747 | | |

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| A 747 | Continued From page 58<br>~exogenous sources of pathogens from the environment, including the air, all tools, instruments, equipment and supplies brought to the surgical field<br>~incident reports of surgical glove perforation during procedures<br>~failures in sterile technique, environmental cleaning, surgical attire, traffic in the OR, sterilization practices, and preoperative antimicrobial prophylaxis.<br><br>In addition, there was no documentation the infection control committee included perioperative nurses in the surveillance program for SSI. | A 747 | | |
| A 843 | 482.43(e) REASSESSMENT OF DISCHARGE PLANNING PROCESS<br><br>The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.<br>This STANDARD is not met as evidenced by:<br>Based on document review and interviews with staff, the hospital failed to monitor readmission rates.<br><br>Findings:<br><br>The hospital's "Quality Assessment, Performance Improvement (QAPI) & Patient Safety Council" meeting minutes, dated 07/01/2015, documented, "... Reduction of readmission outcomes has been monitoring readmissions in regards to after hospital services used such as home health and nursing homes or skilled units..."<br><br>Surveyors reviewed a hospital document titled, | A 843 | | |

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| A 843 | Continued From page 59<br>"Quality and Safety: Readmissions," for readmissions during the time period from December 2014 to August 2015. There was no documentation of inpatient or surgical patient readmissions to the hospital, although the hospital staff stated there were many readmissions.<br><br>On the afternoon of 08/18/2015, Staff C stated the document was not valid information for all readmissions because the data was limited to the movement of patients from acute care beds to swing beds and to home health services. | A 843 | | |
| A 886 | 482.45(a)(1) OPO AGREEMENT<br><br>Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of hospital documents and staff interviews, the hospital did not ensure the Organ Procurement Organization (OPO) was notified of all individuals who died in the hospital.<br><br>Findings: | A 886 | | |

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| A 886 | Continued From page 60<br>A policy titled, "Organ/Tissue Donation and Retrieval, dated September 1987, documented, "... Nursing Supervisor... calls organ procurement coordinator within 60 minutes of each death..."<br><br>The hospital's death log for 2015 documented 32 patient deaths.<br><br>An OPO referral sheet had no documentation patient deaths on 02/05/2015, 04/07/2016, 04/13/2015, 04/22/2015, 05/16/2015 and 07/19/2015 were reported to the OPO.<br><br>On 08/18/2015, staff C stated the Quality Assessment and Performance Improvement (QAPI) committee did not ensure all hospital deaths were reported to the OPO. | A 886 | | |
| A 940 | 482.51 SURGICAL SERVICES<br><br>If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation, interview and document review, it was determined the hospital failed to:<br><br>a. ensure all surgical procedures were performed under acceptable conditions and in locations appropriate for surgery. See also tags A-0700 Physical Environment and A-0747 Infection Control; | A 940 | | |

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| A 940 | Continued From page 61 | A 940 | | |

b. provide an organizational chart for the surgery department and appoint a physician chief of surgery;

c. integrate surgical services into the hospital's QAPI program. See Tag A-0263 QAPI;

d. provide a written and approved scope of surgical services; and

e. the hospital failed to develop and implement current policies and procedures for the provision of surgical services.

Findings:

1. At the time of the survey, surgical spine procedures were performed in the radiology department. The infection control committee, the medical staff and the governing body had not evaluated the radiology department environment for the provision of surgical procedures.

2. The hospital was asked to provide an organizational chart for the surgery department. None was provided. The VP of Patient Care Services was asked to provide the name of the physician appointed as the chief of surgery. An untitled list of "supervising physicians" was provided. The hospital had no documentation that a chief of surgery had been formally appointed by the medical staff and the governing body.

3. The hospital did not provide a written and approved scope of surgical services.

4. The policies and procedures provided for surgical services were incomplete, outdated or

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| A 940 | Continued From page 62<br>missing. They did not accurately reflect the scope of services provided by the department. The policies had no documentation they were developed based on national standards of practice. The hospital did not provide all the policies and procedures as required in this Condition of Participation. | A 940 | | |
| A1028 | 482.53(a)(1) DIRECTOR OF NUCLEAR MEDICINE<br><br>There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of hospital documents and interviews with hospital staff, the hospital failed to ensure a qualified physician was the director of the nuclear medicine department.<br><br>Findings:<br><br>In the morning of 08/13/2015, Staff D stated Staff BB was the director of the hospital's nuclear medicine department.<br><br>Surveyors reviewed the credential file for Staff BB on the afternoon of 08/18/2015. The credential file for Staff BB did not contain evidence of training or education in nuclear medicine.<br><br>On the afternoon of 08/18/2015 at 2:00p.m., Staff JJ stated he was responsible for the credential files. Staff JJ was asked for documentation of nuclear medicine training and education for Staff BB. None was provided. | A1028 | | |